

Job Title : Assistant/Clinical Trial Manager

Department : STCC - Clinical Trials and Investigational Medicine Units

Business Entity: STCC

Overview

The Consortium for Clinical Research and Innovation, Singapore (CRIS) brings together five national R&D, clinical translation and service programmes to advance clinical research and innovation for Singapore, and establish important capabilities for a future-ready healthcare system. The Business Entities under CRIS include:

- Singapore Clinical Research Institute (SCRI)
- National Health Innovation Centre (NHIC)
- Advanced Cell Therapy and Research Institute, Singapore (ACTRIS)
- Precision Health Research, Singapore (PRECISE)
- <u>Singapore Translational Cancer Consortium</u> (STCC)

Together, CRIS makes a positive difference to Singapore patients and researchers by ensuring that these clinical research platforms and programmes are at the cutting edge of capability development and innovation. If you are as passionate as we are in clinical trials and research, we want you!

STCC

The Singapore Translational Cancer Consortium (STCC) is a nationally coordinated consortium to synergise cancer research capabilities in Singapore. Established in 2020, STCC brings together unmatched basic, clinical and translational talent in Singapore to create globally significant peaks of excellence in selected Asian cancers. STCC's four joint platforms – Clinical Trials and Investigational Medicine Units, Cancer Database and Tissue Banks, Research-based Molecular Diagnostics, and Business Intelligence and Development Unit – provide an enabling research and innovation environment driven to foster translational research with meaningful outcomes for society. We currently have the following opening and would like to invite you to be part of an ongoing and dynamic team.

What you will be working on

The Role:

The Assistant Clinical Trial Manager / Clinical Trial Manager will be responsible for the duties and responsibilities listed below:

Primary Responsibilities and Duties

- Oversee the operational readiness of assigned clinical trials within STCC.
- Create and execute study specific tools and documentation.
- Provide oversight, coordination and implementation of the activities, deliverables and study conduct of assigned projects within STCC.
- Manage and liaise with data management on the creation, set up, testing, maintenance of database and database lock for clinical trials.
- Oversee the data entry and cleaning process for data analysis by data monitoring committee.

- Manage and liaise with biostatistician on the set up of the database, datasets transfer and data analysis for assigned clinical trials.
- Manage and liaise with drug safety/pharmacovigilance team on the set up of safety reporting
 processes and templates and coordinate with the sites on the safety reporting process for
 regulatory/ethics submission.
- Manage and liaise with external vendors on the study drug receipt, distribution, storage, inventories, return and destruction of study drugs according to trial SOPs at the site pharmacy.
- Manage and liaise with pharmaceutical companies/biotech companies and site pharmacists on study drug estimation and shipment for assigned clinical trials.
- Manage site monitoring and site close-out activities as per trial monitoring plan till trial completion.
- Evaluate monitoring reports to confirm appropriate conclusions and actions taken.
- Perform oversight on the Clinical Research Associates (CRA) to ensure site level issues are addressed.
- Oversee clinical research study conduct and provide advice to sites to ensure smooth site preparation and running of study within timelines.
- Preparation of training materials for site selection visits, start-up meetings, study audits/inspections etc
- Conduct site initiation trainings and ad-hoc trainings to sites.
- Set up, maintain, supervise and routinely review the electronic trial master file for accuracy, timeliness and completeness.
- Manage external/central laboratory activities according to trial SOPs and laboratory manual.
- Manage the procurement, purchase and delivery of vendor services, liaise between the sites and central laboratory to address any lab/sample issues.
- Discuss and execute study timelines, resource allocation, trial logistics and clinical trial processes with investigator and/or pharmaceutical companies.
- Ensure all trial deliverables are met according to timelines, budget, quality and SOPs, with compliance with GCP and set guidelines
- Assist in the development and review of the clinical trial protocol and study-related documents
- Manage and train the assigned support staff on audit, monitoring, project management and reporting activities.
- Manage STCC tumour groups related activities which include development of documents and facilitation of meetings.

What we are looking for

Qualification

 Minimum Bachelor's degree in life sciences, nursing, pharmacy, medical science or equivalent preferred.

Experience

- At least 3 years of experience in clinical research in a Pharmaceutical Company, or CRO
- Possess knowledge of Good Clinical Practice (GCP), clinical trial monitoring, drug development process, regulatory requirements, project management and medical terminology.

Skills

- Have strong communication, time management, analytical and problem-solving skills.
- Ability to take initiative and work independently and in a team.
- Excellent communication skills, both written and spoken.
- Good organizational and interpersonal skills.
- Resourceful, with good work ethics.
- Meticulous with an attention for details.
- Flexibility and ability to multi-task and meet deadlines.
- Proficient in Microsoft office including Power Point, Excel, Word, etc.

What you need to know

Successful candidate will be offered a 3-year renewable contract. Please send your application to career@cris.sg with the subject **Application for** Assistant/Clinical Trial Manager, STCC. We regret that only shortlisted candidates will be contacted. For more information about CRIS and the Business Entities, visit our websites below:

- o CRIS https://www.cris.sg
- o SCRI https://www.scri.edu.sg
- o NHIC https://www.nhic.sg
- o ACTRIS https://www.actris.sg
- o PRECISE https://www.npm.sg
- o STCC https://www.stcc.sg